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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/056,858	Applicant(s) BLAND ET AL.	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-156 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-156 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20040512</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 19 July, 2004 after a Final action mailed 18 February 2004. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 18 February 2004 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed on 19 July, 2004 has been entered. Accordingly an RCE has been established and the action on RCE follows.
2. Applicants' responsive Amendment filed 19 July, 2004 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

CLAIMS STATUS

3. Claims 1-82 have been cancelled.
4. Claims 83- 156 have been added.
5. Claims 83-156 are pending and are examined on Merits.

Objection To Claims

6. Claim 141 is objected to because of the phrase " rice protein concentration". Applicants should appropriately define/ spell out this phrase.

Claim Rejections Under 35 U.S.C. § 112

7. Claims 83-156 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - The phrase "hormone imbalance" in claims 83 and 153-156 renders those claims indefinite because it is not clear what is meant by the phrase, ""hormone imbalance". The metes and bounds for said phrase are not defined. Applicants should clarify the phrase "hormone imbalance".
 - Phrase, "synergistic beneficial effect" renders Claims 83 and 154-155 unclear and therefore indefinite because said phrase is a relative term and mere perception of a person looking at them. This term is subjective and therefore, does not establish any

metes and bounds to distinguish this term from another. Applicants should define metes and bounds for the phrase "synergistic beneficial effect".

- The recitation, "derived" in claims 84-85, 144 and 149 is unclear as well as confusing, and therefore, indefinite because this term does not clearly define as to how similar a material should be to the base material to be called a derivative, i.e. the term does not define the metes and bounds of the claimed subject matter.
- Claims 92, 104-107, 152-153 and 156 are rendered vague and indefinite because of the term "extract". This term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by process since product-by-process claims are intended to define products that are otherwise difficult to define (and/or distinguish from the prior art). For example, from what part(s) of the plant is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the necessary functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the steps(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (DED. Cir. 1991). Accordingly, without the recitation of all these critical limitations as set forth above, the cited claims do not adequately define the instant invention.
- The recitation, "derivative (s)" in claims 108, 115-120, 131 and 154 is unclear as well as confusing, and therefore indefinite because this term does not clearly define as to how similar a compound should be of the base compound to be called derivative, i.e. the term does not define the metes and bounds of the claimed subject matter. Appropriate correction is required.
- The phrase "simple sugar" renders claim 142 indefinite because it is not clear what is meant by said phrase. The metes and bounds for said phrase are not defined. Applicants should clarify the phrase "simple sugar".

- Claims 151-156 fail to further limit the subject matter claimed in claims 83, 92 and 108. The subject matter claimed in Claim 151 is the same as the combined subject matter in Claims 83, 92 and 108. Furthermore, Claim 155 fails to limit the subject matter claimed in Claim 154.

All other claims depend directly/indirectly from the rejected claims (e.g., Claim 83) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claims Rejections Under 35 U.S.C §103(a)

8. Claims 83-156 are rejected under 35 U.S.C. § 103 (a) as obvious over Cope (U.S. Patent 5,330,972) in view of Clark et al. (U.S. Patent 5,837,256) and Yang et al. (U.S.2002/0025360).

Claims recite a nutritional composition comprising isoflavone, isoflavone synergist and methylation support compound for estrogen metabolites. In said composition,

- (a) isoflavone is obtained from one among: kudzu root, soy, legumes, alfalfa, clover or licorice root,
- (b) isoflavone synergist source is one among: curcumin, rosemary extract or resveratrol, and
- (c) the methylation support compound is a component selected from choline, trimethylglycine, cobalamin, folic acid, riboflavin, pyridoxine or magnesium.
- (d) Additionally, said composition comprises one ingredient selected from the groups constituting vitamins, minerals, fortifying amino acids, carotenoids and flavonoids, and at least one ingredient from the group consisting of proteins, carbohydrates, lipids, lipid modulator and dietary fiber wherein,
 - i. Vitamins is at least one among Vitamins AC, D, E, K, biotin, niacin, pantothenic acid, pyridoxine, riboflavin and thiamin;
 - ii. Mineral is at least one among calcium, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium and zinc;
 - iii. Fortifying amino acid is at least one amino acid among: N-acetylcysteine, L-lysine and L-threonine;
 - iv. Carotenoid is at least one compound among β -carotene, lutein, lycopene and zeaxanthin;
 - v. Flavonoids at least one compound among: chrysin, hesperidin complex, and quercetin;
 - vi. Protein is one among rice protein or rice flour;

- vii. Carbohydrate is one among: α -D-ribofuranose, fructose, rice syrup solids, sucrose and xylitol;
- viii. lipid is canola oil;
- ix. lipid modulator is choline; and
- x. dietary fiber in form of lignan is obtained from flaxseed.

Cope teaches a composition comprising fructose, sucrose, canola oil, choline, soy polysaccharides/protein hydrolysate, cobalamin, folic acid, lysine, threonine, beta carotene, calcium, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, sodium, selenium, zinc, vitamins: A, C, D, E, K, biotin, cyanocobalamin, folic acid, pyridoxine, riboflavine and thiamin (Column 5, Lines 40-68; Column 6, Lines 10 and 13; Column 8, Line 6; Column 9, Lines 56-58; Column 14, Line 28, Tables 7 and 8). Cope's composition is deficient in dietary fiber, flavonoid and isoflavone synergist.

Clark et al. teach a composition comprising flaxseed lignan (Column 3, Lines 1-4, Tables 1 and 2) and Yang et al. teach a food composition comprising curcumin, lycopene, hesperidin or quercetin (Page 5, Column 1, Paragraph 35, Lines 5-19), i.e. components constituting isoflavone synergists and flavonoids. Note that in the specification of instant application, applicants admit on record that nutrients, for e.g., B vitamins, magnesium, limonene, calcium D-glucanate, and antioxidants influences estrogen metabolism and said influence "can have profound significance for diseases in which these hormones can play a role in clinical expression" (Specification, Page 2, Lines 8-10). In the Summary of invention section of the Specification, applicants further state that "A certain embodiment provides a medical composition for treating hormone imbalance comprising a mixture of macronutrients comprising at least one ingredient selected from the group consisting of protein, carbohydrates, and lipids; and micronutrients comprising isoflavone, isoflavone synergist, and methylation support compound" (See Specification, Page 9, Lines 11-18). Thus, applicants admit on record that their composition is a nutrient composition to treat hormonal imbalance. Applicants' invention is obvious in view of combined teachings of the prior art references because the prior art references teach the same source and same component obtained from said sources (e.g., lignan from flaxseed) as is recited in the claimed invention. Thus, the prior art intrinsically teaches a source of dietary fiber or other nutrient compositions/components as is recited in the instantly claimed invention. Therefore, the compositions disclosed in the Examiner-cited prior art references intrinsically

teach "a medical food for treating hormone imbalance" because the composition taught in prior art references is the same as instantly claimed and would therefore, intrinsically would have the same effect in an individual upon ingestion of said composition as is recited in the instantly claimed invention. The instantly claimed invention also remain obvious to an artisan of ordinary skill because the functional intended use of a composition does not materially change a composition and is accordingly, not given any patentable weight.

An artisan of ordinary skill would be motivated to combine the teachings from each one of the cited references because each one of the cited prior art references teach a composition comprising macronutrient and micronutrient components recited in the claimed invention. While, Clark et al. remedy the deficiency of flaxseed lignan as the source of dietary fiber (Column 3, Lines 1-4, Tables 1 and 2) in Cope's composition (Column 5, Lines 40-68; Column 6, Lines 10 and 13; Column 8, Line 6; Column 9, Lines 56-58; Column 14, Line 28, Tables 7 and 8), Yang et al. remedy the deficiencies of curcumin, lycopene, hesperidin or quercetin (Page 5, Column 1, Paragraph 35, Lines 5-19) in teachings from Cope and Clark et al. None of the above discussed prior art references teach rice flour or rice protein as the protein source. kudzu root as source of isoflavone or the same quantities of isoflavone, isoflavone synergists, methylation support compounds. However, the adjustment of particular conventional working conditions (e.g., the quantities of each one of components or sources of those components, pH, temperature etc.) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Cope according to the teachings from Clark et al., and Yang et al's teachings to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. , In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore,

the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. In response to the rejections to Claims 1-80 in the Office Action mailed 18 February 2004, applicants argue that the claimed invention is unobvious over the cited reference, because the cited reference does not disclose, teach, incite or suggest, or provide motivation to arrive at the presently claimed invention because the prior art references do not administer their respective claimed compositions to treat same ailment as instantly claimed.

Applicants' arguments regarding rejections to Claims 1-80 under 35 U.S.C. §103(a) in Office Action mailed 18 February 2004 have been fully considered but are not persuasive for the reasons of record at pages 2-3 of the Office Action cited *supra*, and the discussion presented in item 9 *supra*.

In response to applicants' arguments to the rejections to Claims 1-80 in the Office Action mailed 18 February 2004 against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at pages 4-5 of the Office Action mailed on 20 May 2003, on pages 2-3 of the Office Action mailed 18 February 2004 and in the discussion at item 9 *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and

does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).


CONCLUSION

10. No Claims are allowed.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571) 272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571) 272-0923

September 28, 2004


RALPH GITOMER
PRIMARY EXAMINER
GROUP 1201